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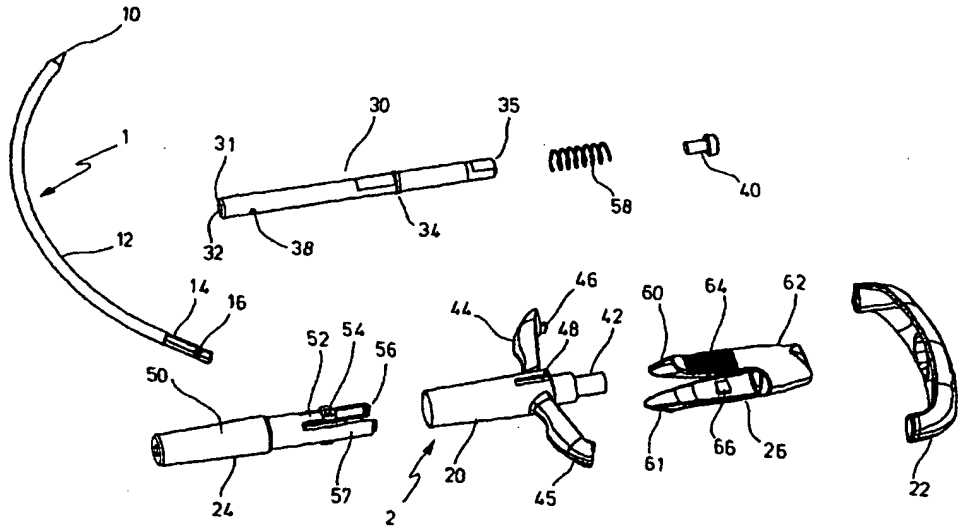
(54) Title: SYSTEM WITH A SURGICAL NEEDLE AND A HANDLE



(57) Abstract: In a system with a surgical needle (1) and a handle (2), the surgical needle (1) has in its proximal end-section, lying opposite the needle tip, a holding section (14), which is set up for insertion into the handle (2). The handle (2) has a channel (32), set up for holding the holding section (14) of the surgical needle (1), and a locking device (50, 70) with a locking element (50) which is displaceable in longitudinal direction of the channel (32) from a locking position, in which the holding section (14) is fixed to the handle (2), into a release position, in which the holding section (14) can be pulled out from the channel (32).

WO 03/017848 A1

System with a surgical needle and a handle

The invention relates to a system with a surgical needle and a handle.

There are surgical techniques in which thick to very thick surgical needles are used, e.g. needles with a diameter of 2 mm to 7 mm. Such needles are used for example in order to insert a tape underneath the urethra of a patient for the treatment of stress incontinence.

Such a large needle can often be handled by the operator only with difficulty. If the needle is guided through tissue, considerable forces arise. The operator can admittedly use a needle holder or a forceps-like surgical instrument when handling the needle. However, as a rule, he often has to reattach this instrument to the needle, which is awkward. Furthermore, unfavourable leverage conditions can occur, in particular if the instrument runs at an angle to the needle.

In the case of a previously known system with a surgical needle and a handle, the handle to which the proximal end-region of the needle lying opposite the tip of the needle is attached facilitates handling. A screw screwed into the proximal face of the needle serves to secure it. In order to pull the needle completely through the body tissue of the patient, the needle has to be detached from the handle. This is awkward, however, because to do this the screw has to be unscrewed first.

It is the object of the invention to provide a possibility of facilitating the handling of a surgical needle, in particular a thick surgical needle.

This object is achieved by a system with a surgical needle and a handle with the features of claim 1. Advantageous versions of the invention emerge from the dependent claims. Claim 15 relates to a surgical needle and claim 16 to a handle which are set up for such a system.

The system according to the invention contains a surgical needle and a handle. In its proximal end-region lying opposite the needle tip, the surgical needle has a holding section which is set up for insertion into the handle. The handle has a channel set up for holding the holding section of the surgical needle and a locking device. The locking device has a locking element which is displaceable in longitudinal direction of the channel from a locking position in which the holding section is attached to the handle, into a release position in which the holding section can be pulled out from the channel.

If the holding section is locked at or fixed to the handle, the surgical needle is firmly and securely connected to the handle. In this position, the handle substantially facilitates the handling of the needle. Thus, e.g., the needle can be held and guided with the help of the handle if it is moved towards the tissue of a patient, placed in position there and pushed through. The suture material, the tape or a similar object which is to be pulled through the tissue with the help of the needle, can be attached to the shaft of the surgical needle between the holding section and the needle tip, preferably near the holding section, e.g. with the help of a shrink-on tube. For this purpose the surgical needle preferably has, distal to the holding section, an attachment section for a suture material, tape or similar, e.g. a section of the shaft, provided with grooves, which can also be provided with a step, against which e.g. the shrink-on tube lies, in order to facilitate a continuous transition between the shaft and the suture material, tape or similar.

If the surgical needle has penetrated the body roughly up to the shoulder of the handle, the needle tip has already left the tissue at the desired point where it or the section of the shaft following the needle tip can be gripped manually by the operator (or with a customary instrument). At this time, the locking element can be moved quickly and in a user-friendly manner from the locking position into the release position, so that the needle can be pulled out of the handle without jerking and expending little force (or conversely the handle can be pulled off the needle). The needle can be pulled fully through the tissue, after the release of the handle, with the suture material, tape or similar attached to the needle.

The surgical needle can have a diameter of 2 mm to 7 mm, however another diameter is also conceivable.

The holding section of the surgical needle preferably deviates from a circular form at least in part of its cross-section, and the channel of the handle is matched in its cross-section to the holding section to secure the surgical needle against twisting. This design makes it possible in an easy way to connect the needle to the handle, secured against rotation.

The channel preferably extends from an opening in the distal end area of the handle, and the holding section of the surgical needle is set up for longitudinal insertion into this opening.

In a preferred version of the invention, the holding section of the surgical needle has at least one recess, in which in the locking position at least one blocking element provided on the locking device of the handle engages. The blocking element is mounted moveable transversely to the longitudinal direction of the channel, the locking element blocking a movement of the blocking element when in the locking position, but freeing it when in the release position. The blocking element preferably includes a ball which projects, when in the locking position,

into the internal space of the channel and, when the needle is inserted, engages in the recess at the holding section of the needle. The channel is preferably formed in a metal sleeve, the ball guided in a recess in the wall of the metal sleeve, and the diameter of the ball is greater than the thickness of the wall in the area of the recess. The locking element can have a sleeve which can be displaced in longitudinal direction of the metal sleeve and which surrounds the metal sleeve, which sleeve has a conical inner surface in the area of the ball and engages against the ball when in the locking position and permits a radial shift of the ball when in the release position.

This preferred design of the invention allows for a convenient and secure handling of the surgical needle. When needed, the locking element can be conveniently and quickly pushed into the release position with the help of an activating element provided on the handle, so that the surgical needle can be released from the handle with slight exertion of force. A further advantage of this version is that plastic can be used as basic material for the handle; through the use of the metal sleeve (which can be cheaply produced) the highly-stressed channel area acquires a stability which is sufficient to secure the holding section of the surgical needle.

Preferably, a spring biases the locking element into the locking position. This guarantees that, in normal position, the surgical needle is locked at the handle. In addition, a safety device can be provided on the handle which is set up to secure the locking element against an unintentional movement into the release position (which could occur even against the spring force). In order to activate the safety device, an ergonomically designed activating element is preferably provided which can be coupled with the activating element for displacing the locking element.

The handle is preferably made substantially from plastic and can be designed as a disposable article. It preferably has a multi-

part housing, so that the locking device can be fitted without any problems.

In a preferred version of the invention, the handle has at least one widening structure in the area of its proximal end, which allows the handle to rest comfortably in the palm of the hand or against the ball of the hand of the operator. The handle can additionally have at least one finger-rest structure, e.g. two wing-like structures extending on opposite sides, which run parallel to the widening structure and with the help of which the operator can e.g. pull the handle onto the palm of his hand with the index finger and the middle finger, so that it rests securely in his hand. A further advantage of this version can be observed when the needle is bent. The operator can then deduce from the position of the widening structure or the finger-rest structure the direction in which the front (distal) section of the needle is running.

The invention is explained in more detail in the following, using an embodiment. The drawings show in

Figure 1 an exploded view of a version of the system according to the invention,

Figure 2 a top view of the handle of the version from Figure 1 when fitted,

Figure 3 a side view of the handle of the version from Figure 1 when fitted,

Figure 4 a longitudinal section through a slightly modified version of the handle when fitted,

Figure 5 a longitudinal section through the distal area of the handle with the surgical needle inserted, which illustrates the locking position, and

Figure 6 a longitudinal section through the distal area of the handle with the surgical needle inserted, which illustrates the release position.

Figure 1 is an exploded view of a version of a system with a surgical needle 1 and a handle 2 and shows the individual parts of the embodiment.

The surgical needle 1, which forms a component of the system, has a needle tip 10 at its distal end. Connected to this is a shaft 12 which is bent in the embodiment and has a maximum diameter of 5 mm. In its proximal end-section the needle 1 has a holding section 14, which is designed with a hexagonal cross-section. A groove-like recess 16 extends over the circumference of the holding section 14 (see also Figure 5 and Figure 6).

Represented in the lower part of Figure 1 are four parts of the handle 2 which, in the embodiment, are each made in one piece from plastic, namely a housing part 20, a handle end-piece 22, a locking element 24 and an activating element 26. How these parts as well as a metal sleeve 30, which is shown in the upper part of Figure 1, are assembled, can be best seen from an overall view of Figures 1 to 4. In short, the metal sleeve 30 is located in the housing part 20 and is, like the handle end-piece 22, firmly connected to it; the locking element 24 and the activating element 26 are locked together and can be displaced in longitudinal direction of the handle 1 relative to the other parts.

The metal sleeve 30 consists of stainless steel, in the embodiment. Extending in longitudinal direction from its open distal end 31 is a channel 32 which has a hexagonal cross-section in its distal section and can accommodate the holding section 14 of the needle 1 completely and securely against rotation. The metal sleeve 30 contains a projecting collar 34 in its central area and an internal thread for accommodating a screw in the area of

its proximal end 35. In the proximity of the distal end 31, the wall 36 of the metal sleeve 30 is provided with two recesses 38, see also Figure 6. The cross-section of the holding section 14 and the cross-section of the channel 32 matched to this, deviate from the shape of an equilateral hexagon, so that the needle 1 can be inserted into the channel 32 only in an unequivocal way.

With the help of a screw 40 which is screwed into the internal thread at the proximal end 35 of the metal sleeve 30, the metal sleeve 30 is attached to the proximal end-section 42 of the housing part 20. The metal sleeve 30 is secured against rotation by a flattened area near its proximal end 35.

The housing part 20 contains two finger-rest structures 44 and 45, at the end of each of which a locking projection 46 is located. The locking projections 46 project into corresponding recesses on the handle end-piece 22, in order to connect the handle end-piece 22 firmly to the housing part 20. Furthermore, the wall of the housing part 20 is provided with a slit 48 and an identical slit lying diametrally opposite this.

The locking element 24, which is designed in one piece in the embodiment, but which in principle can also consist of several parts, has in its distal section a sleeve 50 which, when fitted, surrounds the metal sleeve 30. Two spring tongues 52 extend from the sleeve 50, which are each provided with a locking projection 54 at their ends, and two guiding parts 56 and 57, which are somewhat longer than the spring tongues 52. When the handle 2 is fitted, the locking projections 54 project through the slits 48.

A compression spring 58, which is guided by the metal sleeve 30 and rests against it (not shown in Figure 4), presses against the locking element 24, so that the locking element 24 is so pre-stressed that in the "normal state" (i.e. without exposure to external force) it is displaced in proximal direction relative to the metal sleeve 30 (locking position, see Figure 5).

The activating element 26 contains two side parts 60 and 61, which extend from an end piece 62 and are provided with gripping grooves 64 on their outsides. A locking recess 66 is located on the insides of each of the side parts 60 and 61. When fitted, the locking recesses 66 are locked with the locking projections 54 projecting through the slits 48. The activating element 26 and the locking element 24 are thereby connected to each other. In order to displace the locking element 24 with the help of the activating element 26 relative to the housing part 20 and the metal sleeve 30 and against the force of the compression spring 58, the two side parts 60 and 61 of the activating element 26 must be pressed against each other in order to release a catch arranged on the locking projections 54 and the slits 48 (not shown in detail in the figures). This serves as safety device, so that the locking element 24 cannot be displaced by mistake. The design of the activating element 26 with the two side parts 60 and 61 and the gripping grooves 64 is ergonomic and allows a problem-free operation with surgical gloves.

The mode of operation of the locking device is obvious from Figures 5 and 6; it enables the surgical needle 1 to be either connected firmly and securely to the handle 2 or else released, so that it can be pulled out of the channel 32 without any problems.

Figure 5 shows the locking position in which the holding section 14 is secured to the handle 2. A ball 70 is guided in each of the recesses 38, which extend in the area of the channel 32 and the holding section 14 through the wall 36 of the metal sleeve 30. As the recesses 38 are designed in a slightly conical manner, the balls 70 cannot fall inwards into the channel 32. A radial movement outwards is possible, on the other hand, the sleeve 50 preventing the ball in question 70 from emerging fully from the recess 38. In the area of the balls 70, the sleeve 50 has a conical inner surface 72. In the locking position, the conical inner surface 72 lies against the balls 70, while the

balls 70 engage in the recess 16 on the holding section 14 of the needle 1. As the balls 70 cannot escape outwards in this position, the needle 1 cannot be pulled out of the channel 32. In this position, it is thus securely and firmly connected to the handle 2.

If the two side parts 60 and 61 of the activating element 26 are pressed against each other and the explained safety device is thereby released, the locking element 24 with the sleeve 50 can be displaced relative to the metal sleeve 30, that is to the left in the representation according to Figures 5 and 6. When the release position shown in Figure 6 is reached, the balls 70 are no longer prevented from moving outwards radially. The needle 1 can therefore be pulled out of the channel 32, the groove-like recess 16 pressing the balls 70 radially outwards.

Claims

1. System with a surgical needle (1) and a handle (2),
- wherein the surgical needle (1) in its proximal end-section lying opposite the needle tip (10) has a holding section (14) which is adapted for insertion into the handle (2), and
- wherein the handle (2) has a channel (32), adapted for holding the holding section (14) of the surgical needle (1), and a locking device (24, 70) with a locking element (24), which is displaceable in longitudinal direction of the channel (32) from a locking position, in which the holding section (14) is fixed to the handle (2), into a release position, in which the holding section (14) can be pulled out from the channel (32).

2. System according to claim 1, characterized in that the holding section (14) of the surgical needle (1) deviates from a circular form in its cross-section, at least in a partial area, and the channel (32) of the handle (2) is matched in its cross-section to the holding section (14) to secure the surgical needle (1) against twisting.

3. System according to claim 1 or 2, characterized in that the channel (32) extends from an opening in the distal end area of the handle (2) and the holding section (14) of the surgical needle (2) is adapted for longitudinal insertion into this opening.

4. System according to one of claims 1 to 3, characterized in that the holding section (14) of the surgical needle (1) has at least one recess (16), in which in the locking position at least one blocking element (70) provided on the locking device (24, 70) of the handle (2) engages.

5. System according to claim 4, characterized in that the blocking element (70) is mounted moveable transversely to the longitudinal direction of the channel (32), the locking element (24) blocking a movement of the blocking element (70) when in the locking position, but freeing it when in the release position.

6. System according to claim 5, characterized in that the blocking element includes a ball (70) which projects, when in the locking position, into the internal space of the channel (32) and, when the needle (1) is inserted, engages in the recess (16) at the holding section (14) of the needle (1).

7. System according to claim 6, characterized in that the channel (32) is formed in a metal sleeve (30), the ball (70) is guided in a recess (38) in the wall (36) of the metal sleeve (30) and the diameter of the ball (70) is greater than the thickness of the wall (36) in the area of the recess (38).

8. System according to claim 7, characterized in that the locking element (24) has a sleeve (50) displaceable in longitudinal direction of the metal sleeve (30) and surrounding the metal sleeve (30), which sleeve (50) has a conical inner surface (72) in the area of the ball (70) and engages against the ball (70) when in the locking position, and permits a radial shift of the ball (70) when in the release position.

9. System according to one of claims 1 to 8, characterized in that a spring (58) biases the locking element (24) into the locking position.

10. System according to one of claims 1 to 9, characterized in that a safety device is provided on the handle (2), which

is adapted to secure the locking element (24) against an unintentional movement into the release position.

11. System according to claim 10, characterized in that the safety device has an ergonomically designed activating element (26).

12. System according to one of claims 1 to 11, characterized in that the handle (2) has at least one widening structure (22) in the area of its proximal end.

13. System according to one of claims 1 to 12, characterized in that the handle (2) has at least one finger-rest structure (42, 45).

14. System according to one of claims 1 to 13, characterized in that the surgical needle (1) has, distal to the holding section (14), an attachment section for a suture material, tape or similar.

15. Surgical needle which is set up for a system with a surgical needle (1) and a handle (2) according to one of claims 1 to 14.

16. Handle which is set up for a system with a surgical needle (1) and a handle (2) according to one of claims 1 to 14.

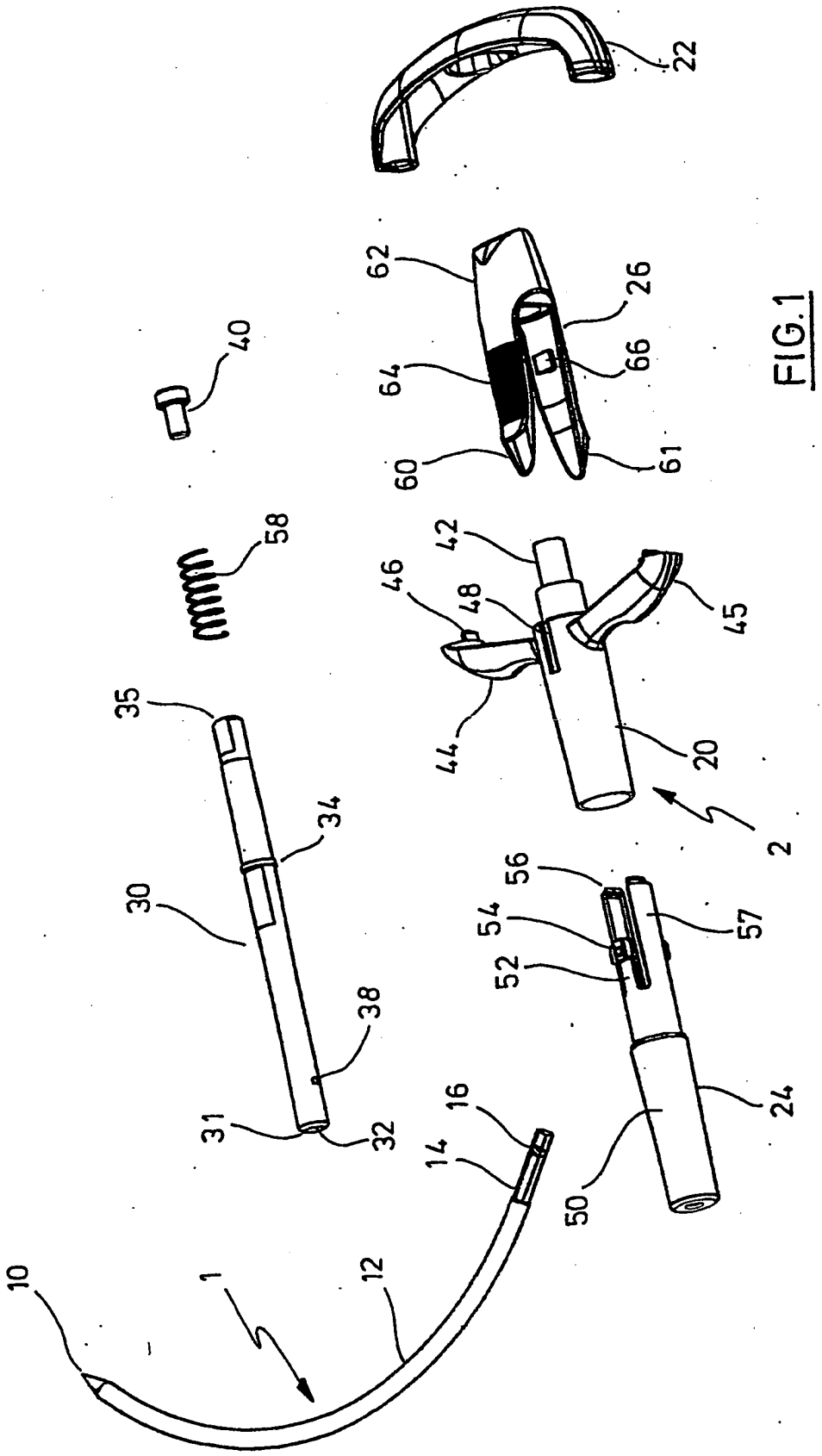

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FIG.1

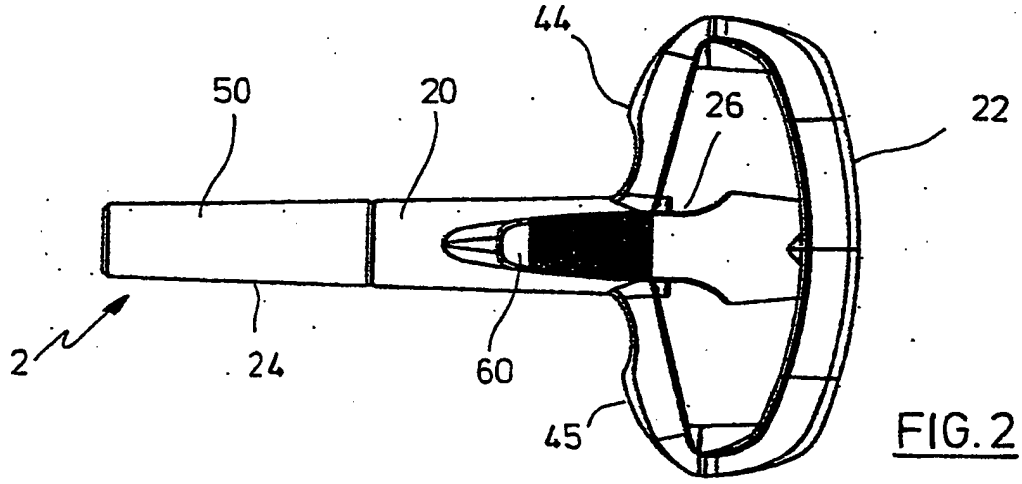

FIG.2

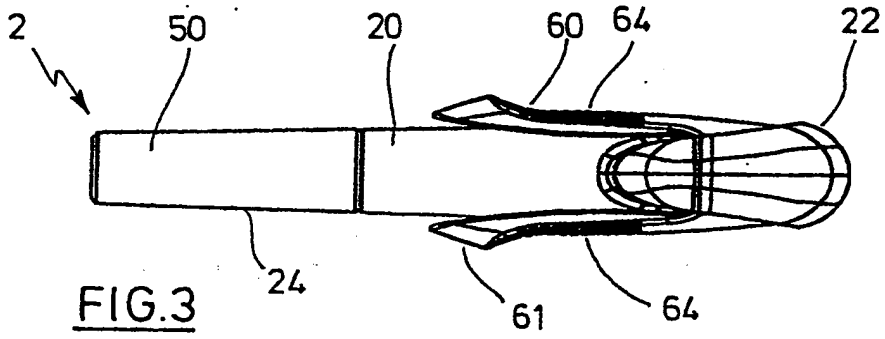

FIG.3

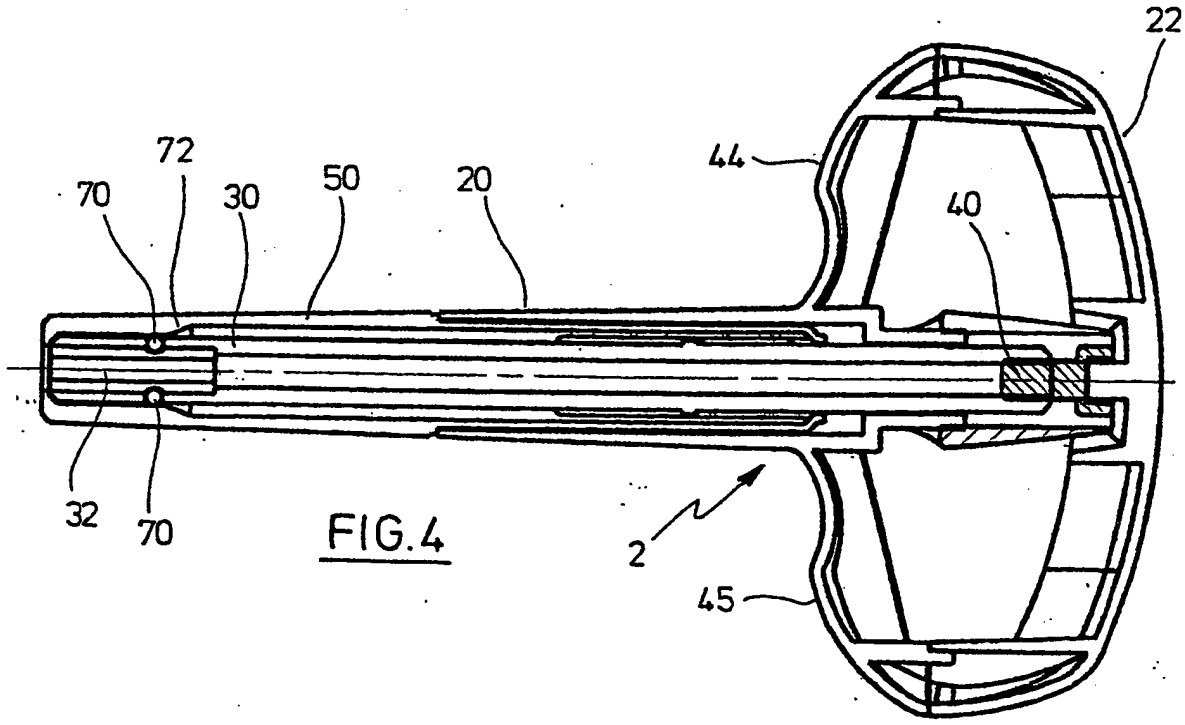

FIG.4

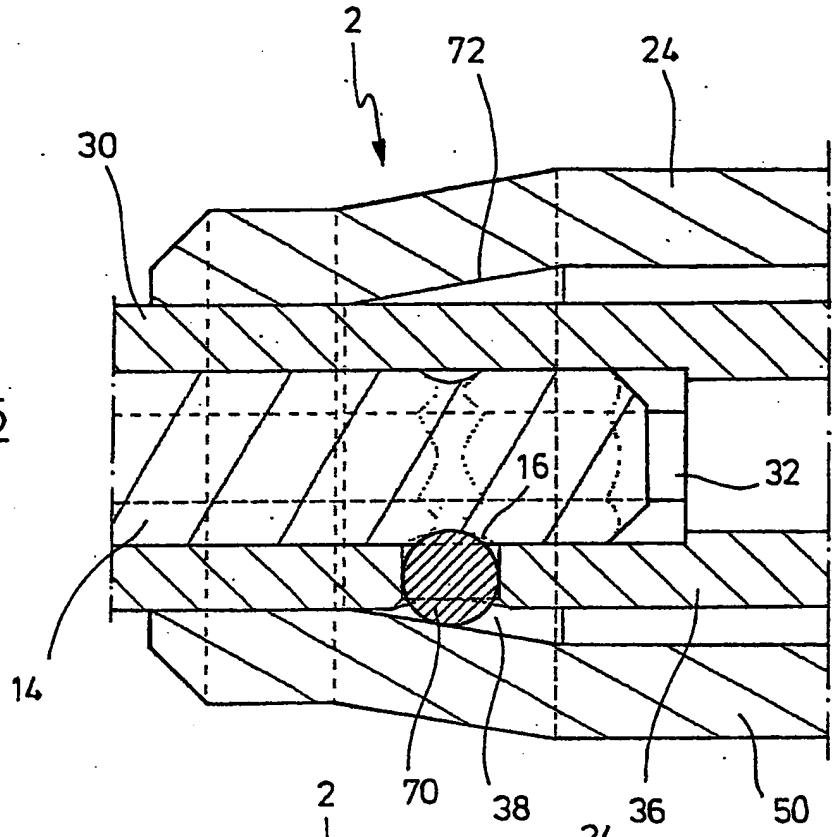

FIG.5

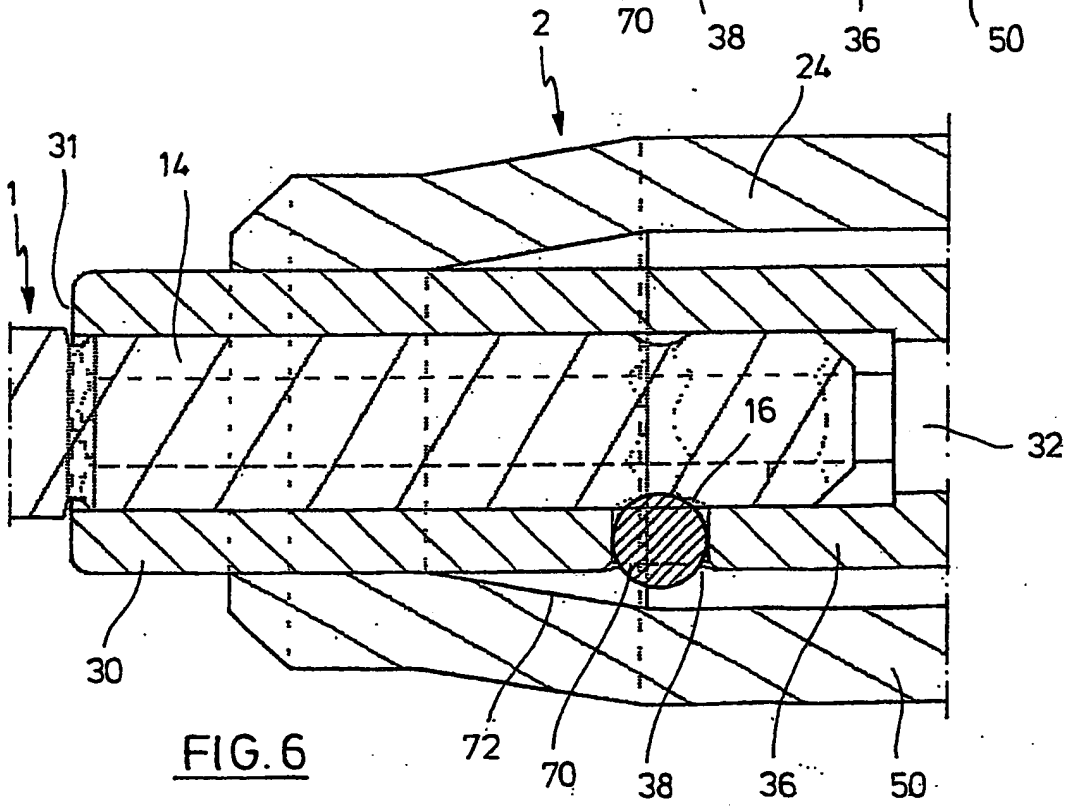

FIG.6

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/06048

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 06567 A (MEDSCAND AB ;KB ULMUS (SE); CLAREN JAN (SE); ULMSTEN ULF (SE)) 7 March 1996 (1996-03-07) page 2, line 30 -page 4, line 31; figures 1-3	1-4, 12-14
X	US 5 603 718 A (XU ZHONGREN) 18 February 1997 (1997-02-18) column 4, line 22 - line 46; figure 6	1,9-11
A	US 5 474 543 A (MCKAY HUNTER A) 12 December 1995 (1995-12-12) column 3, line 9 - line 50; figure 3	1,4-6
A	EP 1 093 758 A (KALADELFOS GEORGE) 25 April 2001 (2001-04-25) column 6, line 4 - line 44	1

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 September 2002	15/10/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Angeli, M

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/06048

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 030 393 A (CORLEW EARVIN L) 29 February 2000 (2000-02-29) the whole document -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 02/06048

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 15-16
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 15-16

Claims 15 and 16 are not clear (Article 5 PCT), as first, its subject-matter is described by non-technical features, namely its suitability, and second, it is not clear whether the needles and the handles, respectively, refer to the same feature or to two different features. Therefore, no search has been done on claims 15 and 16.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 02/06048

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9606567 A	07-03-1996	SE	503271 C2	29-04-1996
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